



GENELABS
TECHNOLOGIES
INCORPORATED

Study #: GL 95-02

Patient No.

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Phase III, GL701

Patient Initials

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Principal Investigator: _____

Date:

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SLAM ASSESSMENT PAGE 1

VISIT: ☐ Screening ☐ Qualifying ☐ 1 ☐ 2 ☐ 3 ☐ Completion/Early Termination ☐ Other
WEEK: (0) (13) (26) (39) (52)

Constitutional

	ABSENT or NORMAL	MILD/ MODERATE	SEVERE	NOT RECORDED
1. Weight Loss	<input type="checkbox"/> 0	<input type="checkbox"/> 1 < 10% body weight	<input type="checkbox"/> 3 > 10%	<input type="checkbox"/>
2. Fatigue	<input type="checkbox"/> 0	<input type="checkbox"/> 1 No limits on activity	<input type="checkbox"/> 3 Functional limitation	<input type="checkbox"/>
3. Fever	<input type="checkbox"/> 0	<input type="checkbox"/> 1 37.5 - 38.5 °C	<input type="checkbox"/> 3 > 38.5 °C	<input type="checkbox"/>

Integument

	ABSENT	MILD	MODERATE	SEVERE	NOT RECORDED
4. Oral/nasal ulcers, or periungual erythema, malar rash, photosensitive rash, or nail fold infarct	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Present			<input type="checkbox"/>
5. Alopecia	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Hair loss with trauma	<input type="checkbox"/> 2 Spontaneous hair loss		<input type="checkbox"/>
6. Erythematous, maculopapular rash, discoid lupus, lupus profundus, or bullous lesions	<input type="checkbox"/> 0	<input type="checkbox"/> 1 < 20% total body surface TBA	<input type="checkbox"/> 2 20 - 50% TBA	<input type="checkbox"/> 3 > 50% TBA	<input type="checkbox"/>
7. Vasculitis (leucocytoclastic vasculitis, urticaria, palpable purpura, livedo reticularis, ulcer or panniculitis)	<input type="checkbox"/> 0	<input type="checkbox"/> 1 < 20% TBA	<input type="checkbox"/> 2 20 - 50% TBA	<input type="checkbox"/> 3 > 50% TBA or necrosis	<input type="checkbox"/>

Eye

	ABSENT	MILD	MODERATE	SEVERE	NOT RECORDED
8. Cytoid bodies	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Present		<input type="checkbox"/> 3 Visual acuity < 20/200	<input type="checkbox"/>
9. Hemorrhage (retinal or choroidal) or episcleritis	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Present		<input type="checkbox"/> 3 Visual acuity < 20/200	<input type="checkbox"/>
10. Papillitis or pseudotumor cerebri	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Present		<input type="checkbox"/> 3 Visual acuity < 20/200 or field cut	<input type="checkbox"/>

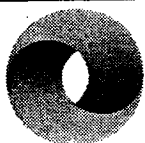
Visit ☐ ☐
Type Interim Completion/
Early Term.

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Investigator's Initials: _____

Date: _____ - _____ - _____

GL-0102 Rev. 2/96



GENELABS
TECHNOLOGIES
INCORPORATED

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Phase III, GL701

Principal Investigator: _____

Patient No. _____

Patient Initials _____

Date: ____-____-____

SLAM ASSESSMENT PAGE 2

VISIT: ☐ Screening ☐ Qualifying ☐ 1 (13) ☐ 2 (26) ☐ 3 (39) ☐ Completion/Early Termination (52) ☐ Other
WEEK: (0)

Reticuloendothelial

	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
11. Diffuse lymphadenopathy (cervical, axillary, epitrochlear)	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Shotty	<input type="checkbox"/> 2 > 1cm X 1.5cm		<input type="checkbox"/>
12. Hepato - or splenomegaly	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Palpable only with inspiration	<input type="checkbox"/> 2 Palpable without inspiration		<input type="checkbox"/>

Pulmonary

	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
13. Pleural effusion/ pleurisy	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Shortness of breath or pain only with prompting. exam normal or near normal	<input type="checkbox"/> 2 Shortness of breath or pain with exercise, decreased breath sounds and dull lower lobe(s)	<input type="checkbox"/> 3 Shortness of breath or pain at rest, decreased breath sounds and dull middle and lower lobe(s)	<input type="checkbox"/>
14. Pneumonitis	<input type="checkbox"/> 0	<input type="checkbox"/> 1 X-ray infiltrates only	<input type="checkbox"/> 2 Shortness of breath with exercise	<input type="checkbox"/> 3 Shortness of breath at rest	<input type="checkbox"/>

Cardiovascular

	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
15. Raynaud's	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Present			<input type="checkbox"/>
16. Hypertension	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Diast. 90-105	<input type="checkbox"/> 2 Diast. 105-115	<input type="checkbox"/> 3 Diast. > 115	<input type="checkbox"/>
17. Carditis	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Pericarditis by EKG &/or RUB &/or effusion by echo; no sx	<input type="checkbox"/> 2 Chest pain or arrhythmia	<input type="checkbox"/> 3 Myocarditis with hemodynamic compromise &/or arrhythmia	<input type="checkbox"/>

Gastrointestinal

	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
18. Abdominal pain (Serositis, pancreatitis, ischemic bowel, etc.)	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Complaint	<input type="checkbox"/> 2 Limiting pain	<input type="checkbox"/> 3 Peritoneal signs/ascites	<input type="checkbox"/>

Neuromotor

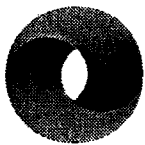
	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
19. Stroke syndrome (includes mononeuritis multiplex, transient ischemic attack (TIA), reversible ischemic neurologic deficit (RIND), cerebrovascular accident (CVA), retinal vascular thrombosis)	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Single TIA	<input type="checkbox"/> 2 Multiple TIA/RIND or mononeuritis multiplex or cranial neuropathy or chorea	<input type="checkbox"/> 3 CVA/myelitis, retinal vascular occlusion	<input type="checkbox"/>
20. Seizure	<input type="checkbox"/> 0	<input type="checkbox"/> 1 1-2/month	<input type="checkbox"/> 2 > 2/month	<input type="checkbox"/> 3 Status epilepticus	<input type="checkbox"/>

Visit ☐ Interim ☐ Completion/
Type Early Term.

Investigator's Initials: _____

Date: ____-____-____

GL-0103 Rev. 2/96



GENE LABS
TECHNOLOGIES
INCORPORATED

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Phase III, GL701

Principal Investigator: _____ Date: ____-____-____

Patient No. _____

Patient Initials _____

SLAM ASSESSMENT PAGE 3

VISIT: ☐ Screening ☐ Qualifying ☐ 1 ☐ 2 ☐ 3 ☐ Completion/Early Termination ☐ Other
WEEK: (0) (13) (26) (39) (52)

Neuromotor (continued)

	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
21. Cortical dysfunction	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Mild depression/ personality disorder or cognitive deficit	<input type="checkbox"/> 2 Δ in sensorium, severe depression, or limiting cognitive impairment	<input type="checkbox"/> 3 Psychosis, dementia, or coma	<input type="checkbox"/>
22. Headache (including migraine equivalents)	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Symptoms or transient neuro deficit	<input type="checkbox"/> 2 Interferes somewhat with normal activities	<input type="checkbox"/> 3 Incapacitating/ aseptic meningitis	<input type="checkbox"/>
23. Myalgia/myositis	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Complaint	<input type="checkbox"/> 2 Limits some activity	<input type="checkbox"/> 3 Incapacitating	<input type="checkbox"/>

Joints

	ABSENT or NORMAL	MILD	MODERATE	SEVERE	NOT RECORDED
24. Joint pain from synovitis and/or tenosynovitis	<input type="checkbox"/> 0	<input type="checkbox"/> 1 Arthralgia only	<input type="checkbox"/> 2 Objective inflammation	<input type="checkbox"/> 3 Limited function	<input type="checkbox"/>

Laboratory

	NORMAL	MILD	MODERATE	SEVERE	UNKNOWN NOT RECORDED
25. Hematocrit	<input type="checkbox"/> 0 > 35	<input type="checkbox"/> 1 30 - 35	<input type="checkbox"/> 2 25 - 29.9	<input type="checkbox"/> 3 < 25	<input type="checkbox"/>
26. WBC	<input type="checkbox"/> 0 > 3500	<input type="checkbox"/> 1 3500 - 2000	<input type="checkbox"/> 2 2000 - 1000	<input type="checkbox"/> 3 < 1000	<input type="checkbox"/>
27. Lymphocyte count	<input type="checkbox"/> 0 1500 - 4000	<input type="checkbox"/> 1 1499 - 1000	<input type="checkbox"/> 2 999 - 500	<input type="checkbox"/> 3 < 499	<input type="checkbox"/>
28. Platelet count	<input type="checkbox"/> 0 > 150T	<input type="checkbox"/> 1 100 - 150T	<input type="checkbox"/> 2 99 - 50T	<input type="checkbox"/> 3 < 50T	<input type="checkbox"/>
29. ESR (westergren)	<input type="checkbox"/> 0 < 25	<input type="checkbox"/> 1 25 - 50	<input type="checkbox"/> 2 51 - 75	<input type="checkbox"/> 3 > 75	<input type="checkbox"/>
30. Serum creatinine or creatinine clearance	<input type="checkbox"/> 0 0.5 - 1.3mg/dl or 80 - 100% CrCt	<input type="checkbox"/> 1 1.4 - 2mg/dl or 79 - 60% CrCt	<input type="checkbox"/> 2 2.1 - 4mg/dl or 30 - 60% CrCt	<input type="checkbox"/> 3 > 4mg/dl or < 30% CrCt	<input type="checkbox"/>
31. Urine sediment	<input type="checkbox"/> 0	<input type="checkbox"/> 1 > 5 RBC &/or WBC/hpf &/or 0 to 1-3 granular &/or cellular casts /hpf &/or 1-2+ proteinuria &/or 500 mg/L 24° urine protein	<input type="checkbox"/> 2 > 10 RBC &/or WBC/hpf &/or > 3 granular &/or cellular casts/hpf &/or 3 or 4+ &/or > 500 mg/L-3.5 g/L 24° urine protein	<input type="checkbox"/> 3 > 25 RBC or WBC/hpf &/or Red cell cast &/or > 4+ proteinuria &/or > 3.5 g/L 24° urine protein	<input type="checkbox"/>

Visit ☐ _____
Type Interim Completion/
Early Term.

Investigator's Initials: _____ Date: ____-____-____

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Principal Investigator: _____

Patient No. _____

Patient Initials _____

Visit Date: ____-____-____

SLEDAI SCORE

VISIT: ☐ Screening ☐ Qualifying ☐ 1 ☐ 2 ☐ 3 ☐ Completion/Early Termination ☐ Other
WEEK: (0) (13) (26) (39) (52)

Check box: If descriptor is present at the time of visit or in the preceding 10 days.

Wt.	Present	Descriptor	Definition
8	<input type="checkbox"/>	Seizure	- Recent onset. Exclude Metabolic, infectious or drug cause.
8	<input type="checkbox"/>	Psychosis	- Altered ability to function in normal activity due to severe disturbance in the perception of reality. Include hallucinations, incoherence, marked loose associations, impoverished thought content, marked illogical thinking, bizarre, disorganized, or catatonic behavior. Exclude uremia and drug causes.
8	<input type="checkbox"/>	Organic Brain Syndrome	- Altered mental function with impaired orientation, memory or other intellectual function, with rapid onset and fluctuating clinical features. Include clouding of consciousness with reduced capacity to focus, and inability to sustain attention to environment, plus at least two of the following: perceptual disturbance, incoherent speech, insomnia or daytime drowsiness, or increased or decreased psychomotor activity. Exclude metabolic, infectious or drug causes.
8	<input type="checkbox"/>	Visual Disturbance	- Retinal changes of SLE. Include cytoid bodies, retinal hemorrhages, serous exudate or hemorrhages in the choroid, or optic neuritis. Exclude hypertension, infection, or drug causes.
8	<input type="checkbox"/>	Cranial Nerve Disorder	- New onset of sensory or motor neuropathy involving cranial nerves.
8	<input type="checkbox"/>	Lupus Headache	- Severe persistent headache; may be migrainous, but must be non-responsive to narcotic analgesia.
8	<input type="checkbox"/>	CVA	- New onset of cerebrovascular accident(s). Exclude arteriosclerosis.
8	<input type="checkbox"/>	Vasculitis	- Ulceration, gangrene, tender finger nodules, periungual infarction, splinter hemorrhages, or biopsy or angiogram proof of vasculitis.
4	<input type="checkbox"/>	Arthritis	- More than 2 joints with pain and signs of inflammation (i.e. tenderness, swelling, or effusion).
4	<input type="checkbox"/>	Myositis	- Proximal muscle aching/weakness, associated with elevated creatine phosphokinase/adolase or electromyogram changes or a biopsy showing myositis.
4	<input type="checkbox"/>	Urinary Casts	- Heme-granular or red blood cell casts.
4	<input type="checkbox"/>	Hematuria	- >5 red blood cells/high power field. Exclude stone, infection or other cause.
4	<input type="checkbox"/>	Proteinuria	- >0.5 gm/24 hours. New onset or recent increase of more than 0.5 gm/24 hours.
4	<input type="checkbox"/>	Pyuria	- >5 white blood cells/high power field. Exclude infection.
2	<input type="checkbox"/>	New Rash	- New onset or recurrence of inflammatory type rash.
2	<input type="checkbox"/>	Alopecia	- New onset or recurrence of abnormal, patchy or diffuse loss of hair.
2	<input type="checkbox"/>	Mucosal ulcers	- New onset or recurrence of oral or nasal ulcerations.
2	<input type="checkbox"/>	Pleurisy	- Pleuritic chest pain with pleural rub or effusion, or pleural thickening.
2	<input type="checkbox"/>	Pericarditis	- Pericardial pain with at least 1 of the following: rub, effusion, or electrocardiogram confirmation.
2	<input type="checkbox"/>	Low complement	- Decrease in CH50, C3, or C4 below the lower limit of normal for testing laboratory.
2	<input type="checkbox"/>	Increased DNA binding	- >25% binding by Farr assay or above normal range for testing laboratory.
1	<input type="checkbox"/>	Fever	- >38° C. Exclude infectious cause.
1	<input type="checkbox"/>	Thrombocytopenia	- <100,000 platelets/mm ³ .
1	<input type="checkbox"/>	Leukopenia	- <3,000 White blood cells/mm ³ . Exclude drug causes.

____ TOTAL SCORE (Sum of weights next to descriptors marked present)

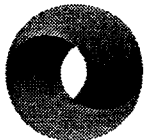
Visit ☐ ☐
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Principal Investigator: _____

Patient No. _____

Patient Initials _____

Visit Date: ____-____-____

PATIENT SELF-ASSESSMENT QUESTIONNAIRE

VISIT: ☐ Screening ☐ Qualifying ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Completion/
WEEK: (0) (4) (8) (13) (26) (39) (52) Early Termination ☐ Other

SELF-ADMINISTERED BY THE PATIENT: We are interested in learning whether or not you are affected by fatigue because of your illness, as well as the overall effects of your illness on your general well-being.

- 1) Circle a number between 1 and 7 that indicates your degree of agreement with each of the statements below for the past week, where 1 indicates that you strongly disagree and 7 means that you strongly agree.

	DISAGREE					AGREE	
	1	2	3	4	5	6	7
a) My motivation is lower when I am fatigued.							
b) Exercise brings on my fatigue.							
c) I am easily fatigued.							
d) Fatigue interferes with my physical functioning.							
e) Fatigue causes frequent problems for me.							
f) My fatigue prevents sustained physical functioning.							
g) Fatigue interferes with carrying out certain duties and responsibilities.							
h) Fatigue is among my three most disabling symptoms.							
i) Fatigue interferes with my work, family or social life.							

- 2) Please indicate on the scale below, using a vertical line, how you have felt in the past week (including psychological and physical factors).

No problems at all The worst I have ever felt

Score:

(for Genelabs use only)

Visit ☐ ☐
Type Interim Completion/
Early Term.
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Date: ____-____-____

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